Male Contraceptive Initiative
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Male Contraceptive Initiative
2025 Request For Applications (RFA)

Research Applications due:	**August 1st, 2025**
Anticipated award notification:	**December 2025**

Section I: Funding Opportunity Description

Purpose: Nearly half of all pregnancies worldwide are unintended. Furthermore, male contraceptives are limited to condoms and vasectomy, which do not provide adequate variety in characteristics to meet the needs of all users.

Male Contraceptive Initiative (MCI), a US-based 501(c)3 nonprofit, is a funding agency and advocate for safe, effective, and reversible contraceptive solutions for sperm-producing people. This funding opportunity provides support for research projects related to the development of reversible non-hormonal contraceptives that could be delivered to men.

Key Points: The state of the male contraceptive field has advanced to a place where many programs are beyond discovery stages of development, i.e. have progressed through target identification and hit discovery and are in the stages of hit-to-lead optimization. MCI seeks to support programs carrying out these next set of steps required to generate candidates appropriate for Good Laboratory Practice / Good Manufacturing Practice (GLP/GMP)-stage development and IND-enabling studies.

By enhancing our focus on the stages of development where we see opportunity, we aim to support programs advancing to the point where they are eligible for other funding streams including venture capital (VC) funding, accelerate the development of multiple product types, and bring new products to market more efficiently.

Therefore, this RFA supports preclinical research on drug-based, non-hormonal, reversible male contraceptives in stages ranging from hit-to-lead chemistry through early preclinical studies. Funding amounts range from $200,000-$400,000 for a two-year project. MCI seeks proposals that demonstrate proof-of-concept, have advanced through early discovery, and have a pathway to clinical studies. The goal of this funding application is to support the development of a pipeline of small molecule preclinical male contraceptive assets ready for Investigational New Drug (IND) enabling studies.

Award Details

Scope

Envisioned eligible project activities include but are not limited to:

- Employ structure-based drug design techniques to optimize hit compounds.
- *In vitro* assessment of ADMET properties for compounds with potential male contraceptive activity.
- Chemical modifications of a lead compound or series to enhance its potency, selectivity, or absorption, distribution, metabolism, excretion, and toxicity (ADMET) profile.
- Conduct preformulation studies to characterize the physicochemical properties of a lead compound and develop a suitable formulation for preclinical *in vivo* studies.
- A demonstration of the efficacy and safety of a lead compound in a relevant animal model, including preliminary pharmacokinetic / pharmacodynamic (PK/PD) data.
- Compare the PK/PD properties of multiple lead compounds to identify the most promising candidate for further development.
- Design and test a novel delivery system (i.e. long-acting injectable, transdermal patch) for a pre-selected and optimized compound.
- Investigate the mechanism of action of a lead compound's contraceptive effect, including its interaction with the cognate target and potential downstream signaling pathways.

Promising applications may:

- Focus on a specific, well-justified target with a known mechanism of action and a lead compound with promising *in vitro* data.
- Have a well-defined set of cell-based or *in vitro* target binding and / or selectivity assays to be used in structure-activity relationship (SAR) and lead development.
- Build upon existing hit-to-lead work and focus on optimizing a specific lead series.
- Focus on improving the PK/PD profile of a known active compound.
- Focus on the head-to-head comparisons of identified lead compounds.
- Focus on characterizing the safety profile of a novel chemical series.
- Have a detailed intellectual property strategy or other strong commercialization plan.
- Have a well-defined Target Product Profile (TPP), and a clear biological justification for why the approach can lead to a contraceptive product matching the TPP's characteristics.

Applications must focus on a genetically validated target, pharmacologically validated molecule or a new/improved delivery mechanism for a pharmacologically validated molecule:

- For the purposes of this announcement, validation is defined as a demonstration that the proposed approach will result in a contraceptive effect. Means of achieving validation include but are not limited to:
    - Genetic Target Validation:
        - Targeted deletion of a gene that results in complete male infertility in a mammalian animal model without other significant adverse phenotypes.
        - Inhibited expression of the gene encoding the target through RNAi or another gene silencing method that results in infertility as demonstrated by a secondary method such as mating studies or *in vitro* fertilization.
        - Clinical evidence that a target is directly responsible for infertility in men, without other significant adverse phenotypes.
    - Pharmacological Validation:
        - Administration of a contraceptive agent in a mammalian animal model, resulting in complete and fully reversible male infertility, without other significant adverse effects at the minimum efficacious dose.
        - On-target pharmacology demonstrating binding effects of a known molecule to a validated contraceptive target

	Applicants are encouraged to submit projects aligned with MCI Priority Research Areas, which include the following approaches: ● Preventing normal sperm production by targeting proteins involved in spermiogenesis. ● Permanently inhibiting or irreversibly altering sperm functions required for normal fertilization, such as sperm motility, capacitation, hyperactivation, and the acrosome reaction. ● Interfering with post-testicular processes required for fertility, including epididymal maturation or sperm transport in the excurrent ducts. ● Approaches with the potential to lead to pre-coital or “on-demand” male contraceptives that offer effective pregnancy prevention after a single dose administered shortly before intercourse. ● Approaches where temporary exposure to a pharmaceutical leads to “durable” changes in sperm which could lead to products that offer longer efficacy windows, reduced user burden, and effectiveness even with imperfect user adherence. Durability could be achieved through the use of tools such as targeted degraders or covalent inhibitors to cause permanent inhibition of a given target, or by demonstrating how temporary pharmaceutical inhibition of the target leads to irreversible functional deficiencies in sperm. ● Approaches that repurpose existing chemical entities for contraception that are currently approved by the US Food and Drug Administration (FDA) or other regulatory agencies for other indications, provided the existing safety profile is compatible with a contraceptive indication. ● Approaches with the potential to lead to Multipurpose Prevention Technology (MPT) products that simultaneously prevent pregnancy and sexually transmitted infections such as HIV.
Eligibility	This application is open to global academic institutions, for-profit organizations, and other entities. Any individual(s) with the skills, knowledge, and internal or external resources necessary to carry out the proposed research as a Principal Investigator (PI) is invited to submit an application through their institution. Projects that are not responsive to this announcement include: ● Proposals focused on contraceptive methods that rely on the manipulation or alteration of hormone levels (i.e. testosterone, follicle-stimulating hormone (FSH), or luteinizing hormone (LH)) or rely on direct binding to steroid hormone receptors. ● Projects aimed at developing permanent contraceptive methods or projects that have been shown to lead to irreversible infertility. ● Proposals based on mechanisms of contraceptive action that may act post-fertilization. ● Proposals focused on contraceptive mechanism of action that could only conceivably function through administration in the female body, i.e. products that may act via the oviduct or uterus, intrauterine devices/intrauterine systems, or products that work through adjusting the consistency of cervical mucus. For the purposes of this announcement, penile or vaginally applied gels are ineligible. ● Proposals focused on molecular targets for which there is no human ortholog. ● Projects proposing to induce active immunity against sperm antigens. ● Proposals whose pharmaceutical mechanism of action involves the disruption of the blood-testis and/or blood-epididymal barriers. ● Proposals focusing on predominantly early discovery stage research – While target validation work on pharmacologically validated molecules that directly supports lead compound development may be considered, projects solely focused on target identification or hit screening are generally outside the scope of this RFA. ● Projects that have advanced to clinical trials (testing in humans) are not eligible for funding under this announcement.

	● Device-focused projects lacking a pharmacologic mechanism - While this RFA does not explicitly exclude device-based approaches, priority is given to projects focused on drug-based non-hormonal contraceptive agents. Device-focused projects will be considered only if they involve a pharmacological mechanism of action (i.e. a device delivering a non-hormonal compound). Purely mechanical device approaches such as physical barriers are ineligible for this specific RFA. ● Proposals that require simultaneous administration of two or more pharmaceuticals or simultaneous inhibition of two or more targets for contraceptive efficacy. ● Proposals focused solely on conducting GLP-compliant IND-enabling studies (i.e. full toxicology assessments, safety pharmacology studies). ● Proposals focused on establishing GMP manufacturing. Small-scale synthesis for research purposes is acceptable. ● Proposals solely focused on formulation development without an *in vivo* application of formulations or other supporting research objectives such as concurrent lead optimization or mechanism of action studies are less competitive. ● Proposals solely focused on structural determination without complementary objectives such as concurrent lead optimization or mechanism of action studies are less competitive. ● Applications lacking preliminary data to support the feasibility and potential of the proposed research (i.e. *in vitro* data for a lead compound, proof-of-concept data in an animal model) will be less competitive. A strong foundation of *in vitro* or *in vivo* preliminary data is expected. ● Projects lacking a well-defined Target Product Profile. ● Projects without a defensible biological justification for how their lead pharmacological compound, if successful, will lead to a contraceptive effect compatible with the applicant's Target Product Profile. ● While not strictly ineligible, proposals involving biologics (i.e. proteins, antibodies) must address specific challenges related to their development, including (but not limited to) target binding and engagement assays, potency and specificity assays, immunogenicity assessment, pharmacokinetic (PK) considerations, manufacturing feasibility (at a research scale), and formulation/delivery strategies. ● Proposals that are not directly related to the development of a potential contraceptive product - i.e. behavioral research or market analysis. Applicants with questions regarding eligibility are encouraged to contact MCI in advance of developing an application.
Maximum Award Budget	Up to $400,000 in total costs for a two-year project, at a maximum of $200,000 per year.
Indirect Costs / Overhead	Institutional indirect costs / overhead shall not exceed 10% of the total award costs listed above in the Maximum Award Budget and are to be included as a part of the Maximum Award Budget.
Award Project Period	Awards may have a maximum Project Period of two years.
Available Funds	MCI may commit up to $1.6 million to fund multiple awards in association with this announcement.

Section II: How to Apply

To start an application, go to the ProposalCentral website at (https://proposalcentral.com/). If you are a new user of ProposalCentral, follow the link marked “Need an Account?” and complete the registration process. If you are already a registered user, login with your username and password or ORCID ID.

Once you are logged in, please click the “Professional Profile” tab at the top and complete steps 1-11 or update with your current information. Your name, degrees, position/title, academic rank, department, and address will be pulled from this page in ProposalCentral.

Next, select the “Grant Opportunities” tab and a list of applications will be displayed. Search for “Male Contraceptive Initiative” and click “Apply Now” on the appropriate opportunity.

In section 11, “Attach Documents Here” the following items A-D must be uploaded, organized into the following sections and subsections with the listed page restrictions:

Required Attachments

A: Research Proposal (not to exceed seven pages, including figures and references):

1. Title / Specific Aims Page:
    a. Applicant’s name, title, institution, and contact information
    b. Collaborator’s (if any) name(s), title, institution, and contact information
    c. Project Title
    d. Research Abstract (up to 250 words)
    e. Specific Aims: Concise summary aims of the project.
2. Background: Concisely describe the state of the field and the need for the proposed research. Provide key published and unpublished data underlying the proposed studies and the relevance of the methods and approaches to be used.
3. Research Plan: Describe Specific Aims, their underlying rationale, the novelty of the approach, questions to be addressed, hypotheses, and predicted outcomes in detail. Describe design and sequence of studies to address Specific Aims. Describe how proposed studies will advance the potential male contraceptive being investigated; address evaluation of the safety, reliability and reversibility of its use; propose potential challenges and alternative approaches.
4. References (up to one page): No specific reference format is required. Many style guides with guidance for citations are available and acceptable.

B: Project Management (up to two pages):

1. Applicant's role and responsibilities in performance of proposed research
2. Roles of key collaborators or contract research organizations (if any)
3. Novel or essential facilities, equipment, and resources available for the proposed studies or how they will be accessed if not available
4. **Milestones**: Expected outcomes and deliverables with quantifiable goals

   All projects must clearly define milestones, or deliverables for each specific aim of the project with quantifiable metrics that define success. To be measurable, each milestone should define success as a specific target value or metric. These target values or metrics should allow for objective evaluation and be structured as go / no-go decisions for each stage of the project.

   Illustrative examples: Express and isolate 10mg of a target protein with a purity of 99%; develop at least 5 compounds across two scaffolds with a sub-nM IC_{50} value as measured by a valid assay; fertility studies at 5 mg/kg will demonstrate complete contraceptive efficacy after no more than 6 weeks; achieve a 50x therapeutic safety window between hERG IC50 and target potency.

Timelines must present objectives and milestones in a written format that details specific activities performed during each quarterly period, and these activities must also be displayed visually in a Gantt Chart.

	2026				**2027**			
	Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3**	**Q4**
Specific Aim 1								
Milestone 1.1								
Milestone 1.2								
Specific Aim 2								
Milestone 2.1								
Sub-objective 2.1								
Milestone 2.3								
Specific Aim 3								
Milestone 3.1								
Milestone 3.2								
Milestone 3.3								

Example Gantt Chart. Chart may be adapted in any way to fit the submitting project. Milestones may be further divided into sub-objectives and other categories as needed such that they provide detailed activities

that can be related directly to the milestones to be achieved.

C: Curriculum Vitae (up to five pages each for applicant and key collaborators; NIH biosketch format is preferred)

1. Education, current and prior positions and appointments
2. Current and prior research experience, sources and amounts of current and prior research support
3. Publications relevant to application

D: Appendix (no page limit):

1. Target/Approach Justification (up to 1 page): This section should provide a comprehensive rationale for the selection of the proposed approach, and provide proof of either genetic target validation or pharmacological validation, as defined above.
    a. Describe the specific target (e.g., protein, enzyme, signaling pathway) or lead molecule and its known function in male reproductive processes. Provide evidence from published literature or preliminary data supporting the target's essential role in fertility or the lead molecule's demonstrated inhibition of fertility in mammalian animal models. Discuss the potential for selective modulation of the target to achieve contraceptive efficacy without significant off-target effects.
    b. Clearly explain the proposed mechanism by which modulating the target will lead to contraception (e.g., inhibition of sperm production, maturation, or function). Address the potential for reversibility of the contraceptive effect. Describe how these mechanisms are compatible with your proposed Target Product Profile.
    c. Discuss the potential for adverse effects associated with modulating the target, based on available preclinical or clinical data.
2. Target Product Profile (up to 2 pages): The Target Product Profile (TPP) outlines the desired characteristics of the final male contraceptive product. Applicants must provide a clear and detailed TPP with minimally acceptable criteria and target criteria that should include, but not be limited to, the following characteristics. Further project-specific criteria are encouraged.
    a. Intended Use and Target Population:
    b. Route of Administration and Dosage:
    c. Efficacy and Duration of Action:
    d. Safety and Tolerability:
    e. Reversibility:
    f. Product Stability and Storage:
3. Letters of support: Letters of support must be provided for all budgeted collaborators and subcontractors. Other letters of support are encouraged as appropriate. Letters of support should describe the collaborator or subcontractor's ability to successfully perform any experimental activities assigned to them in the Research Plan.
4. (Optional) Intellectual property statement (up to one page): Information about the current or planned intellectual property (IP) position of the compound(s), device(s) or

process(es) described in previous sections may be provided here. Potential topics for an intellectual property statement include, but are not limited to:

   a. University or company IP policy: Summary of any patents, copyrights, trademarks, licenses or other intellectual property owned; Documentation relating to the transfer of any technology to the Company or any employee, consultant or other party; Proprietary Information and Invention Agreements signed by past or present employees and consultants.
   b. Description of the potential patentability of the molecule or approach described in the application.
   c. Description of the landscape of related patents, with mention of any potentially competing patents on related compounds or approaches.

5. (Optional) Supporting information (up to four pages): Examples of supporting information may include but are not limited to:
   a. Supplemental data, supplemental figures, or unique methods and materials
   b. Quotes or other documentation from vendors
6. (Optional) Suggested reviewers (up to one page): Applicants may list up to five suggested reviewers. Applicants may also use this section to list reviewers that they request to be excluded from consideration.

Budget

In section 9, “Budget Detail” provide the following information as an input into the form:

1. Personnel: names, roles in project, percentage of salary and benefits to be covered for each
2. Reagents: cost for general lab consumables can be listed by category, key unique compounds and reagents should be listed individually.
3. Animals: institutional cage costs, number and species to be used. Include IACUC-approved protocol numbers when appropriate
4. Contractors, consultants, and sub-awardees: names, roles in project, brief justification, and studies to be performed. Attach quotes or letters of support in the Appendix
5. Equipment: essential equipment not available and required for project, manufacturer, cost based on bid from supplier (up to a maximum of 10% of the total award amount). Attach quotes in the Appendix.
6. Overhead: maximum of 10% of total award amount. Overhead is to be included as an itemized budget line as part of total award amount, which is not to exceed the maximum award budget listed in Section 1.
7. Cost sharing: Voluntary committed cost-sharing, or matching funds originating from the applicant or other sources is allowed to be included as a budgetary component. If proposing cost sharing, use this section to illustrate non-MCI sources of funding, clear delineations between project costs that are covered by MCI funds and costs that are covered by other sources of funding, and include any related information such as institutional cost-sharing policy. Projects utilizing effective cost-sharing are encouraged.

Section III: Review

Process and Confidentiality

All information submitted as part of the application is treated as confidential unless explicitly stated otherwise, and will be shared only with assigned reviewers, MCI staff, and the members of the MCI research committee.

Applications will be reviewed for scientific and technical merit by an appropriate review panel assembled by MCI. Reviewers will certify adherence to Conflict of Interest and Non Disclosure Rules. Reviewers will be advisory to the MCI Research Committee and the MCI Board of Directors.

All reviewed applications will receive a written critique, which will be anonymized and provided to the applicant as constructive feedback.

The following considerations will be taken into account when making funding decisions:

- Relevance of the proposal to the vision and mission of the organization
- Scientific and technical merit as evaluated by the review panel
- Availability of funds
- Relevance of the proposal to the goals and priorities outlined in the RFA description
- Readiness of the proposal and project to move into later stages of contraceptive development
- Relevance of the proposal to MCI Priority Research Areas
- Relevance of the proposal to a balanced MCI funding portfolio

Review Criteria

- **Significance** (25% weight)
    - Is the proposed project of substantial importance to the field of male contraception?
    - Does it address issues relevant to Male Contraceptive Initiative?
    - Will the project's success lead to a meaningful impact on the field, the address of a gap in knowledge, or the direct development of a novel male contraceptive?
- **Innovation** (15% weight)
    - Does the proposal demonstrate novel and creative ideas?
    - Is there evidence of building upon existing research or incorporating innovative approaches?
- **Research Plan** (30% weight)
    - Are the research questions clearly defined and relevant?

    - Do the proposed methods and techniques align with the research objectives?
    - Is the experimental design well-structured and effectively explained?
    - Are potential limitations or challenges acknowledged, and mitigation strategies proposed?
- **Feasibility** (30% weight)
    - Does the proposed budget align with the scope and complexity of the project?
    - Is the timeline realistic and appropriate to achieve the project's objectives?
    - Are the milestones reasonable and attainable within the allocated resources and timeframe?
    - Are the investigators adequately qualified and equipped to execute the proposed research effectively?
    - Is there evidence of relevant expertise and experience?
    - Is the proposed environment conducive to support the successful completion of the project?

Section IV: Award Administration

A formal notification will be provided to the applicant organization for successful applications. The notification will be signed by the MCI awards management officer and will be sent via email to the grantee.

Applicants are advised to target a project with a start date in Q1 2026. Later start dates are possible. Contract negotiations between MCI and the parent institution may prolong proposed start dates.

MCI expects applicants selected for funding to work with MCI staff in establishing a final milestone plan which will be used to evaluate progress of the award.

Any costs incurred before formal notification of award are at the risk of the awardee, and are not reimbursable.

MCI is required by the IRS to publish a list of awarded grants. MCI also provides general descriptions of its awards on its web sites, in press releases, and in other marketing materials. Awardees may be asked to participate in promotional efforts by MCI, which can include interviews, outreach, and other publicity. These efforts are voluntary, and will not impact the terms of the grant.

Other grantee benefits associated with awards include access to MCI resources, promotional outlets such as webinars and meetings, connection to experts and key opinion leaders, networking opportunities, and other support from MCI staff.

Progress Reports & Monitoring

Continuation of funding beyond the first year is contingent upon satisfactory progress and availability of funds. MCI may arrange for confidential meetings with consultants with relevant expertise to facilitate the development of products resulting from funded projects. MCI may also contract with a third-party monitor to evaluate progress and provide consultation on the project, including evaluation of quarterly benchmarks.

Grantees are responsible for adhering to the approved project proposal. Should changes in project objectives or key personnel be necessary, grantees must contact their MCI awards officer at the earliest possible opportunity to discuss changes and impact on award, as changes may require review from MCI.

Budget variances of more than 10% in any budget subcategory must be approved by MCI. MCI reserves the right to audit any of the relevant records of grantees.

Awardees are responsible for adhering to the Grant Progress Reporting Guide, which will be provided after award notification to successful applicants and can be provided to prospective applicants on request. The Grant Progress Reporting Guide outlines a quarterly update structure through informal email exchanges, written reports, and virtual meetings.

Ongoing funding is to be determined yearly by the MCI Research Committee. The decision of the Research Committee is reached using the quarterly updates detailed in the Grant Progress Reporting Guide and an annual written report, which details progress on proposal-specific milestones.

The annual written report will be due 30 days before the end of the funding year via https://proposalcentral.com/. The Progress Report will be a confidential document and should be submitted in pdf format. It will include:

Research Narrative (Two pages minimum, five pages maximum, include figures when appropriate):

- List the major goals and objectives of the project for the current year and what was accomplished for these goals.
    - Include key outcomes or conclusions (both positive and negative), and a discussion of goals not met.
- Compare research progress against specific milestones and target dates outlined in the project proposal and / or approved by MCI. List the specific milestones for the current year, if / when they were met, and the evidence of successful research progress.
- Explain any changes to original goals and objectives that require modification of research plans. Note that whenever possible, changes in goals, research scope,

approaches, or methods should be communicated to the appropriate MCI contact at the earliest opportunity.
- Describe, in detail, any problems or delays that impacted the project, or potential problems for the upcoming reporting period.

Budget (two pages maximum):

- Provide a proposed budget for the coming year and justify amounts and purposes of planned expenditures. Include a reporting of expenditures to date, and compare against original estimates.

Appendix (optional - no page limit)

- The appendix may be used to provide any additional information that is relevant to the progress of the project. Examples include:
    - Structures of chemical compounds mentioned in the Research Narrative, additional images or figures, relevant data tables, etc.
    - Publications, presentations, media outreach, or other public representations
    - Personal or professional accomplishments from the awardee or staff during the reporting period
    - Inventions, patents, or licenses that have resulted from the award
    - Opportunities for training and professional development
    - Meetings with regulatory authorities, new partnerships, business developments, or leveraged / newly awarded funding

Informal updates and unscheduled communications from the awardee to MCI are welcome and greatly appreciated especially in the event of unexpected challenges, recent accomplishments, or other opportunities.

Open Access

MCI is committed to dissemination of published research resulting from project funds to enable unrestricted access and reuse of all peer-reviewed publications (“Open Access”). Grantees shall publish all publications in a manner that will permit any reader to have access to an article without further permission or fees being required.

Applicants are encouraged to include Open Access publication fees in a prospective budget when applying.

Global Access

After awards are made, MCI requires that grantees establish a Global Access strategy for the products generated, if any, under the Project. Grantees will make a good faith effort to conduct and manage all Project research, product development, technologies and innovations in a manner, consistent with global access commitments, to disseminate knowledge gained during

the conduct of the Project to the scientific community, subject to a limited delay to seek intellectual property protection where such protection would best facilitate the achievement of the Project's charitable objectives, and to work collaboratively to ensure that any products developed from Project Funds are made accessible (with respect to cost, quantity, and applicability) to the people most in need within developing countries and public sector markets in developed countries of the world.

Section V: Contact

Questions regarding any aspect of this announcement are encouraged. Please contact:

Logan Nickels
Chief Research Officer
logan@malecontraceptive.org

Or:

grants@malecontraceptive.org

For technical issues while applying, please contact pcsupport@altum.com.